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Jason D. Kelly Shumaker & Sieffert, P.A. 1625 Radio Drive Suite 300 St. Paul, MN 55125			EXAMINER ALTER, ALYSSA MARGO	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHRISTOPHER PEARCE and DAVID HAMPTON

Appeal 2009-002857
Application 10/762,387
Technology Center 3700

Decided: November 10, 2009

Before TONI R. SCHEINER, DONALD E. ADAMS, and FRANCISCO C.
PRATS, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1-79, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to an apparatus for documenting the myocardial ischemia of a patient's heart (claims 1-21); a method for documenting the myocardial ischemia of a patient's heart (claims 22-39); an apparatus for documenting the myocardial ischemia in a patient's heart (claims 40-61); and a medical apparatus of the type that is configured to monitor the electrocardiogram waveform of a patient (claims 62-79). Claim 1 is illustrative:

1. An apparatus for documenting the myocardial ischemia of a patient's heart, the apparatus comprising:
 - an ECG monitor and data collector configured to receive electrocardial data about the patient's heart;
 - a cardiac marker data collector configured to receive cardiac marker data about the patient's heart; and
 - a data processing and recording module in electrical communication with said ECG monitor and data collector and said cardiac marker data collector and configured to record said electrocardial data and said cardiac marker data, and to generate a prompt to a user to perform a cardiac marker test.

The Examiner relies on the following evidence:

Crosby et al.

US 2005/0004485 A1

Jan. 6, 2005

The rejection presented by the Examiner follows:

Claims 1-79¹ stand rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Crosby (Ans. 3).

We reverse the rejection under 35 U.S.C. § 102(e) and affirm the rejection under 35 U.S.C. § 103(a).

ISSUE

Have Appellants established error in the Examiner's conclusion that Crosby anticipates an apparatus, wherein the data processing and recording module is configured to generate a prompt to a user to perform a cardiac marker test?

FINDINGS OF FACT

FF 1. Appellants do not dispute and therefore concede to the Examiner's finding that Crosby teaches an apparatus comprising an ECG monitor and

¹ Appellants assert that "[t]he Final Office Action dated 05/01/2006 ('Final Action') lists claims 1-78 as pending, and lists claims 1-78 in the claims rejections. Claim 79 is not mentioned in the Action. Applicant has assumed that this is a clerical (typographical) error and references to '1-78' in the Final Action were meant to be '1-79'" (App. Br. 3, n. 1). Appellants identify the grounds of rejection to be reviewed on appeal as including claims 1-79" (App. Br. 5). The Examiner's Answer recognizes that "appellant's [sic] statement of the grounds of rejection to be reviewed on appeal is correct" (Ans. 3). Nevertheless, the Examiner's Answer contains the same "typographical error" as the Final Rejection. Because Appellants recognized the "typographical error" and addressed all the claims, including claim 79, in their Appeal Brief, we will consider claim 79 as part of the Examiner's Rejection before us on appeal.

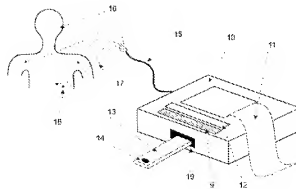
data collector; a cardiac marker data collector; and a data processing and recording module, wherein each collector, monitor, and/or module is configured according to Appellants' claim 1 with the exception of a data processing and recording module that generates a prompt to a user to perform a cardiac marker test (*see generally* Ans. 3-5).

FF 2. Appellants' Specification discloses that "[t]he prompt may be provided as instructions appearing on a visual display, such as [the] patient data display . . . , as a signal light appearing on [the] apparatus . . . , or may be an alarm or other auditory signal, or any other suitable prompt or signal" (Spec. 7: ¶ 0026).

FF 3. Appellants' Specification discloses that the apparatus may be configured to prompt "a user to conduct a cardiac marker test regardless of the ECG data or any interpretation thereof" (*id.*).

FF 4. Crosby teaches an apparatus comprising "an ECG means and an apparatus for reading or conducting a biochemical test using a test strip" (Crosby 7: ¶ 0072).

FF 5. For clarity Crosby's Figure 2 is reproduced below:



“FIG. 2 is a diagrammatic illustration of a device which includes apparatus for ECG analysis in conjunction with apparatus for performing one or more in vitro diagnostic tests” (Crosby 5: ¶ 0041).

FF 6. As illustrated in Crosby’s Figure 2,

[T]he electronic module housing (10) comprises an ECG function means including a means for displaying and/or printing ECG results (11), and a means such as a keyboard by which an operator controls the operation of the machine and enters parameters into the machine (9), and a means by which the operation of the machine is displayed to the operator such as a display panel (12). . . . The module housing has an aperture or slot into which a test strip is inserted (19), and associated means for reading the results of a test strip for one or more biochemical markers. . . . A test strip (13) has a location (14) such as a well for application of a patient sample. The test strip is inserted into the reader means via an aperture or slot (19).

(Crosby 8: ¶ 0073.)

FF 7. The Examiner finds that a “prompting to perform and enter diagnostic data (i.e. a test strip per paragraph 72) . . . would be an inherent part of the Crosby et al. system” (Ans. 4).

PRINCIPLES OF LAW

“[T]he [E]xaminer bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). On appeal to this Board, Appellants must show that the Examiner has not sustained the required burden. *See Ex parte Yamaguchi*, 88 USPQ2d 1606, 1608 and 1614 (BPAI 2008) (precedential).

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). “[A] prior art reference may[, however,] anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.” *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002) (citations and internal quotation marks omitted). “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Obviousness is viewed through the lens of a person of ordinary skill in the art with consideration of common knowledge and common sense. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). It is therefore proper to “take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418. *See also id.* at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”).

ANALYSIS

The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 1 is representative.

Claim 1 is drawn to an apparatus that comprises, *inter alia*, a data processing and recording module that is configured to generate a prompt to a user to perform a cardiac marker test. Appellants do not dispute and therefore concede that Crosby teaches every other element of claim 1 (FF 1).

According to Appellants' Specification a "prompt" may be any "suitable prompt or signal" including instructions on a visual display, a signal light, or an auditory signal (FF 2). The scope of the term "prompt" reads on an indication that is as simplistic as displaying the term "load" on a display, similar to the configuration of any number of prior art CD players that prompt a user through the use of a visual display that the machine is ready to receive/load a CD.

Nevertheless, Appellants contend that Crosby fails to teach, suggest, or imply "a prompt to perform a cardiac marker test" (App. Br. 6 and 7-8).

Anticipation:

Appellants contend that Crosby fails to "explicitly teach a prompt to perform a cardiac marker test" (App. Br. 6). While this may be true a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or *inherently* described, in a single prior art reference." *Verdegaal Bros.*, 814 F.2d at 631 (emphasis added).

Thus, the issue under the anticipation component of the rejection is whether the generation of a "prompt" is inherent in the teachings of Crosby.

Appellants contend that “it cannot be said that the giving of a prompt to perform a cardiac marker test is an inherent part of the Crosby system” (App. Br. 7). We agree. Inherency “may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Robertson*, 169 F.3d at 745. The Examiner has not established a sufficient evidentiary foundation to support a conclusion that Crosby’s apparatus or methods necessarily include a “prompt” as required by Appellants’ claims. *Cf. Cruciferous Sprout Litig.*, 301 F.3d at 1349 (“if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.”)

Obviousness:

We are not persuaded by Appellants’ contention that the apparatus of claim 1 is non-obvious in view of Crosby because it generates a “prompt” (e.g., “load” or a light) indicating that the apparatus is ready to perform an operation and thereby directing a user to take appropriate action, e.g., to perform a cardiac marker test (*see e.g.*, App. Br. 7-8).

Crosby teaches an apparatus with “a means such as a keyboard by which an operator controls the operation of the machine” (FF 6). We find that it would have been *prima facie* obvious to a person of ordinary skill in this art at the time the invention was made that the effective operation of the apparatus would include a “prompt” notifying the operator of the status, operation, and requirements of the machine, including a prompt to a user to perform a cardiac marker test, which Appellants’ admit is a necessary requirement of Crosby’s method (App. Br. 9). Accordingly, we agree with

the Examiner's conclusion that it would have been obvious to include such a "prompt, either audible or visual" in Crosby's apparatus to "yield the predictable results of guiding the operator through the diagnosis process, in order to ensure proper medical care is provided to the patient" (Ans. 4). *Dystar*, 464 F.3d at 1367; *KSR*, 550 U.S. at 418. See also *id.* at 421 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

We are not persuaded by Appellants' contention that their "apparatus makes possible . . . a system in which someone with less expertise than a physician and not carrying out the orders of a physician, can be given the direction needed to know if and when a cardiac marker test should be administered" (App. Br. 9). There is no requirement in claim 1 that the apparatus be used by a practitioner of a particular skill. In addition, a "prompt" would be beneficial regardless of whether the apparatus is used by those who are skilled, unskilled, or both.

Further, Appellants' Specification discloses that the apparatus may be configured to prompt "a user to conduct a cardiac marker test regardless of the ECG data or any interpretation thereof" (FF 3). As Appellants admit "Crosby's method always includes an in vitro assay and the in vitro diagnostic test may be done at any point in the sequence of events" (App. Br. 9). With regard to a particular sequence of events, Appellants have not identified a limitation in the apparatus of claim 1 that would require a diagnostic test to be performed at any particular point in the sequence of events the apparatus is capable of performing. Therefore, we are not persuaded by Appellants' contentions regarding the use of the apparatus to

assist a user determine whether a cardiac test should be performed and/or to perform such a test at a particular point in the sequence of events performed by the apparatus. For the same reasons, we are not persuaded by Appellants' contention that "Crosby's teachings are not concerned with assisting someone in determining whether to administer a test" (*id.*).

CONCLUSION OF LAW

Appellants established error in the Examiner's conclusion that Crosby anticipates an apparatus, wherein the data processing and recording module is configured to generate a prompt to a user to perform a cardiac marker test. Therefore, the rejection of claims 1-79 under 35 U.S.C. § 102(e) as anticipated by Crosby is reversed.

Appellants failed to establish error in the Examiner's conclusion that Crosby makes obvious an apparatus, wherein the data processing and recording module is configured to generate a prompt to a user to perform a cardiac marker test. Therefore, the rejection of claim 1 under 35 U.S.C. § 103 as obvious over Crosby is affirmed. Claims 2-79 fall together with claim 1.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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Application 10/762,387

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